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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-1719-N]

Medicare Program; Public Meeting on June 24, 2019 Regarding New and Reconsidered Clinical Diagnostic Laboratory Test Codes for the Clinical Laboratory Fee Schedule for Calendar Year 2020

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice.

SUMMARY: This notice announces a public meeting to receive comments and recommendations (including data on which recommendations are based) from the public on the appropriate basis for establishing payment amounts for new or substantially revised Healthcare Common Procedure Coding System (HCPCS) codes being considered for Medicare payment under the Clinical Laboratory Fee Schedule (CLFS) for calendar year (CY) 2020. This meeting also provides a forum for those who submitted certain reconsideration requests regarding final determinations made last year on new test codes and for the public to provide comment on the requests.

The Medicare Advisory Panel on Clinical Diagnostic Laboratory Tests (Advisory Panel on CDLTs) will participate in this CLFS Annual Public Meeting by gathering information and asking questions to presenters, and will hold its next public meeting on July 22 and 23, 2019.

The public meeting for the Advisory Panel on CDLTs will focus on the discussion of and recommendations for test codes presented during the June 24, 2019 CLFS Annual Public Meeting. The Panel meeting also will address any other CY 2020 CLFS issues that are designated in the Panel's charter and specified on the meeting agenda.

DATES:

CLFS Annual Public Meeting Date: The meeting is scheduled for Monday, June 24, 2019 from 8:00 a.m. to 4:30 p.m., E.D.T.)

Deadline for Registration of Presenters and Submission of Presentations: All presenters for the CLFS Annual Public Meeting must register **and** submit their presentations electronically to our CLFS dedicated email box at CLFS_Annual_Public_Meeting@cms.hhs.gov, by June 10, 2019 at 5:00 p.m. E.D.T. Any presentations received after that date and time will not be included in the meeting.

Deadline for Submitting Requests for Special Accommodations: Requests for special accommodations must be received no later than 5:00 p.m. E.D.T. on June 10, 2019.

Deadline for Submission of Written Comments Related to the CLFS Annual Public Meeting: Written comments regarding the presentations must be received by July 8, 2019 at 5:00 p.m. E.D.T. (2 weeks after the meeting).

Publication of Proposed Determinations: We intend to publish our proposed determinations for new test codes and our preliminary determinations for reconsidered codes (as described later in this notice in section II. "Format") for CY 2020 by early September 2019.

Deadline for Submission of Written Comments Related to Proposed Determinations: Comments in response to the preliminary determinations will be due by early October 2019.

Where to Submit Written Comments: Interested parties should submit all written comments on presentations and preliminary determinations to the address specified in the "**ADDRESSES**" section of this notice or electronically to our CLFS dedicated email box, CLFS_Annual_Public_Meeting@cms.hhs.gov (the specific date for the publication of these

determinations on the CMS website, as well as the deadline for submitting comments regarding these determinations, will be published on the CMS website).

ADDRESSES: The CLFS Annual Public Meeting will be held in the main auditorium of the Centers for Medicare & Medicaid Services (CMS), Central Building, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

FOR FURTHER INFORMATION CONTACT: Rasheeda Arthur, PhD, (410)786-3434.

Submit all inquiries to the CLFS dedicated email box,

CLFS_Annual_Public_Meeting@cms.hhs.gov with the subject entitled “CLFS Annual Public Meeting Inquiry.”

SUPPLEMENTARY INFORMATION:

I. Background

Section 531(b) of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) (Pub. L. 106-554) required the Secretary of the Department of Health and Human Services (the Secretary) to establish procedures for coding and payment determinations for new clinical diagnostic laboratory tests under Part B of title XVIII of the Social Security Act (the Act) that permit public consultation in a manner consistent with the procedures established for implementing coding modifications for International Classification of Diseases (ICD-9-CM) (now, ICD-10-CM). The procedures and Clinical Laboratory Fee Schedule (CLFS) public meeting announced in this notice for new tests are in accordance with the procedures published on November 23, 2001 in the **Federal Register** (66 FR 58743) to implement section 531(b) of BIPA.

Section 942(b) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108-173) added section 1833(h)(8) of the Act. Section 1833(h)(8)(A)

of the Act requires the Secretary to establish by regulation procedures for determining the basis for, and amount of, payment for any clinical diagnostic laboratory test for which a new or substantially revised Healthcare Common Procedure Coding System (HCPCS) code is assigned on or after January 1, 2005 (hereinafter referred to as “new tests”). A code is considered to be substantially revised if there is a substantive change to the definition of the test or procedure to which the code applies (such as, a new analyte or a new methodology for measuring an existing analyte-specific test). (See section 1833(h)(8)(E)(ii) of the Act and 42 CFR 414.502).

Section 1833(h)(8)(B) of the Act sets forth the process for determining the basis for, and the amount of, payment for new tests. Pertinent to this notice, sections 1833(h)(8)(B)(i) and (ii) of the Act require the Secretary to make available to the public a list that includes any such test for which establishment of a payment amount is being considered for a year and, on the same day that the list is made available, cause to have published in the **Federal Register** notice of a meeting to receive comments and recommendations (including data on which recommendations are based) from the public on the appropriate basis for establishing payment amounts for the tests on such list. This list of codes for which the establishment of a payment amount under the CLFS is being considered for CY 2020 will be posted on the Center for Medicare & Medicaid Services (CMS) website concurrent with the publication of this notice and may be updated prior to the CLFS Annual Public Meeting. The CLFS Annual Public Meeting list of codes can be found on the CMS website at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/index.html?redirect=/ClinicalLabFeeSched/>. Section 1833(h)(8)(B)(iii) of the Act requires that we convene the public meeting not less than 30 days after publication of the notice in the **Federal Register**. The CLFS requirements regarding public consultation are codified at 42 CFR 414.506.

Two bases of payment are used to establish payment amounts for new clinical diagnostic laboratory tests (CDLTs). The first basis, called “crosswalking,” is used when a new CDLT is determined to be comparable to an existing test, multiple existing test codes, or a portion of an existing test code. New CDLTs that were assigned new or substantially revised codes prior to January 1, 2018, are subject to provisions set forth under § 414.508(a). For a new CDLT that is assigned a new or significantly revised code on or after January 1, 2018, CMS assigns to the new CDLT code the payment amount established under § 414.507 of the comparable existing CDLT. Payment for the new CDLT code is made at the payment amount established under § 414.507. (See § 414.508(b)(1)).

The second basis called “gapfilling,” is used when no comparable existing CDLT is available. When using this method, instructions are provided to each Medicare Administrative Contractor (MAC) to determine a payment amount for its Part B geographic area for use in the first year. In the first year, for a new CDLT that is assigned a new or substantially revised code on or after January 1, 2018, the MAC-specific amounts are established using the following sources of information, if available: (1) Charges for the test and routine discounts to charges; (2) resources required to perform the test; (3) payment amounts determined by other payers; (4) charges, payment amounts, and resources required for other tests that may be comparable or otherwise relevant; and (5) other criteria that CMS determines appropriate. In the second year, the test code is paid at the median of the MAC-specific amounts. (See § 414.508(b)(2)).

Under section 1833(h)(8)(B)(iv) of the Act and § 414.506(d)(1), CMS, taking into account the comments and recommendations (and accompanying data) received at the CLFS Annual Public Meeting, develops and makes available to the public a list of proposed determinations with respect to the appropriate basis for establishing a payment amount for each

code, an explanation of the reasons for each determination, the data on which the determinations are based, and a request for public written comments on the proposed determinations. Under section 1833(h)(8)(B)(v) of the Act and § 414.506(d)(2), taking into account the comments received on the proposed determinations during the public comment period, CMS then develops and makes available to the public a list of final determinations of payment amounts for tests along with the rationale for each determination, the data on which the determinations are based, and responses to comments and suggestions received from the public.

Section 216(a) of the Protecting Access to Medicare Act of 2014 (PAMA) (Pub. L. 113-93) added section 1834A to the Act. The statute requires extensive revisions to the Medicare payment, coding, and coverage requirements for CDLTs. Pertinent to this notice, section 1834A(c)(3) of the Act requires the Secretary to consider recommendations from the expert outside advisory panel established under section 1834A(f)(1) of the Act when determining payment using crosswalking or gapfilling processes. In addition, section 1834A(c)(4) of the Act requires the Secretary to make available to the public an explanation of the payment rates for the new test codes, including an explanation of how the gapfilling criteria and panel recommendations are applied. These requirements are codified in § 414.506(d) and (e).

After the final determinations have been posted on the CMS website, the public may request reconsideration of the basis and amount of payment for a new CDLT as set forth in § 414.509. Pertinent to this notice, those requesting that CMS reconsider the basis for payment or the payment amount as set forth in § 414.509(a) and (b), may present their reconsideration requests at the following year's CLFS Annual Public Meeting provided the requestor made the request to present at the CLFS Annual Public Meeting in the written reconsideration request. For purposes of this notice, we refer to these codes as the "reconsidered codes." The public may

comment on the reconsideration requests. (See the CY 2008 Physician Fee Schedule final rule with comment period published in the **Federal Register** on November 27, 2007 (72 FR 66275 through 66280) for more information on these procedures).

II. Format

We are following our usual process, including an annual public meeting to determine the appropriate basis and payment amount for new and reconsidered codes under the CLFS for CY 2020.

This meeting is open to the public. The on-site check-in for visitors will be held from 7:30 a.m. to 8:00 a.m. E.D.T., followed by opening remarks. Registered persons from the public may discuss and make recommendations for specific new and reconsidered codes for the CY 2020 CLFS.

As stated in the “**SUMMARY**” section of this notice, the Advisory Panel on CDLTs will participate in the CLFS Annual Public Meeting on June 24, 2019 by gathering information and asking questions to presenters, and will hold its own public meeting on July 22 and 23, 2019, to discuss matters of the Panel and make recommendations regarding the test codes presented at the CLFS Annual Public Meeting. The announcement for the Advisory Panel on CDLTs meeting is included in a separate **Federal Register** notice.

Due to time constraints, presentations must be brief, lasting no longer than 10 minutes, and must be accompanied by three written copies. In addition, presenters should make copies available for approximately 50 meeting participants, since CMS will not be providing additional copies. Written presentations must be electronically submitted to CMS on or before June 10, 2019. Presentation slots will be assigned on a first-come, first-served basis. In the event there is not enough time for presentations by everyone who is interested in presenting,

CMS will accept written presentations from those who were unable to present due to time constraints. Presentations should be sent via email to our CLFS dedicated email box, CLFS_Annual_Public_Meeting@cms.hhs.gov. In addition, individuals may also submit requests after the CLFS Annual Public Meeting to obtain electronic versions of the presentations. Requests for electronic copies of the presentations after the public meeting should be sent via email to our CLFS dedicated email box, noted above.

Presenters are required to submit all presentations using a standard PowerPoint template that is available on the CMS website, at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Laboratory_Public_Meetings.html, under the “Meeting Notice and Agenda” heading.

For reconsidered and new codes, presenters should address all of the following five items:

- (1) Reconsidered or new codes and descriptor.
- (2) Test purpose and method.
- (3) Costs.
- (4) Charges.
- (5) Recommendation with rationale for one of the two bases (crosswalking or gapfilling)

for determining payment for reconsidered and new tests.

Additionally, presenters should provide the data on which their recommendations are based. Presentations regarding reconsidered and new test codes that do not address the above five items for presenters may be considered incomplete and may not be considered by CMS when making a determination. However, we may request missing information following the meeting to prevent a recommendation from being considered incomplete.

Taking into account the comments and recommendations (and accompanying data) received at the CLFS Annual Public Meeting, we intend to post our proposed determinations with respect to the appropriate basis for establishing a payment amount for each new test code and our preliminary determinations with respect to the reconsidered codes along with an explanation of the reasons for each determination, the data on which the determinations are based, and a request for public written comments on these determinations on the CMS website by early September 2019. This website can be accessed at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/index.html?redirect=/ClinicalLabFeeSched/>. Interested parties may submit written comments on the preliminary determinations for new and reconsidered codes by early October 2019, to the address specified in the “**ADDRESSES**” section of this notice or electronically to our CLFS dedicated email box, CLFS_Annual_Public_Meeting@cms.hhs.gov (the specific date for the publication of the determinations on the CMS website, as well as the deadline for submitting comments regarding the determinations, will be published on the CMS website). Final determinations for new test codes to be included for payment on the CLFS for CY 2020 and reconsidered codes will be posted on the CMS website in November 2019, along with the rationale for each determination, the data on which the determinations are based, and responses to comments and suggestions received from the public. The final determinations with respect to reconsidered codes are not subject to further reconsideration. With respect to the final determinations for new test codes, the public may request reconsideration of the basis and amount of payment as set forth in §414.509.

III. Registration Instructions

The Division of Ambulatory Services in the CMS Center for Medicare is coordinating the CLFS Annual Public Meeting registration. Beginning April 8, 2019, and ending June 10, 2019, registration may be completed on-line at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/index.html?redirect=/ClinicalLabFeeSched/>. On this webpage, under the heading “Meeting Notice, Registration and Agenda,” you will find a link entitled “Register for CLFS Annual Meeting”. Click this link and enter the required information. All the following information must be submitted when registering:

- Name.
- Company name.
- Address.
- Telephone numbers.
- E-mail addresses.

When registering, individuals who want to make a presentation must also specify the new test codes on which they will be presenting comments. A confirmation will be sent upon receipt of the registration. Individuals must register by the date specified in the “**DATES**” section of this notice. Registration is only required for individuals attending the meeting in person.

If not attending the CLFS Annual Public Meeting in person, the public may view the meeting via webcast or listen by teleconference. During the public meeting, webcasting is accessible online at <http://cms.gov/live>. Teleconference dial-in information will appear on the final CLFS Annual Public Meeting agenda, which will be posted on the CMS website when available at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/index.html?redirect=/ClinicalLabFeeSched/>.

IV. Security, Building, and Parking Guidelines

The meeting will be held in a Federal government building; therefore, Federal security measures are applicable. In planning your arrival time, we recommend allowing additional time to clear security. We suggest that you arrive at the CMS campus and parking facilities between 7:00 a.m. and 8:00 a.m. E.D.T., so that you will be able to arrive promptly at the meeting by 8:00 a.m. E.D.T. Individuals who are not registered in advance will not be permitted to enter the building and will be unable to attend the meeting. We note that the public may not enter the CMS building earlier than 7:15 a.m. E.D.T. (45 minutes before the convening of the meeting).

Security measures include the following:

- Presentation of government-issued photographic identification to the Federal Protective Service or Guard Service personnel. Persons without proper identification may be denied access to the building.
- Interior and exterior inspection of vehicles (this includes engine and trunk inspection) at the entrance to the grounds. Parking permits and instructions will be issued after the vehicle inspection.
- Passing through a metal detector and inspection of items brought into the building.

We note that all items brought to CMS, whether personal or for the purpose of demonstration or to support a demonstration, are subject to inspection. We cannot assume responsibility for coordinating the receipt, transfer, transport, storage, set-up, safety, or timely arrival of any personal belongings or items used for demonstration or to support a demonstration.

V. Special Accommodations

Individuals attending the meeting who are hearing or visually impaired and have special requirements, or a condition that requires special assistance, should provide that information

upon registering for the meeting. The deadline for registration is listed in the “**DATES**” section of this notice.

VII. Collection of Information Requirements

This document does not impose information collection requirements, that is, reporting, recordkeeping or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.).

Dated: March 15, 2019.

Seema Verma,

Administrator,

Centers for Medicare & Medicaid Services.